

OCT 12 2001



Microvative Endoscopy  
Boston Scientific Corporation  
One Boston Scientific Place  
Natick, MA 01760-1537  
508-650-8000  
www.bsci.com

**Section 7**  
**510(k) Summary**

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**510(K) SUMMARY**

**1. Submitter:**

Boston Scientific Corporation  
One Boston Scientific Place  
Natick, MA 01760-1537

Contact: Kathleen Morahan  
Principal Regulatory Specialist  
Date Prepared: August 6, 2001

**2. Device:**

**Device Name:**

Ultraflex™ Esophageal Stent System  
Ultraflex™ Diamond Biliary Stent System  
Ultraflex™ Tracheobronchial Stent System

**Common Name:**

Esophageal Prostheses  
Biliary Stent  
Tracheal Prostheses

**Classification Name:**

Esophageal Prostheses  
Biliary Catheter & Accessories  
Tracheal Prostheses

**3. Predicate Device:**

Ultraflex Esophageal Stent System, K940838  
Ultraflex Diamond Biliary Stent System, K962899  
Ultraflex Tracheobronchial Stent System, K963241

**4. Device Description:**

The proposed Esophageal, Biliary, and Tracheobronchial Ultraflex stents are comprised two components, a metallic expandable stent and a flexible delivery catheter. The stents are mounted on a delivery catheter. The delivery catheter is placed over a guidewire and through the working channel of an endoscope to deliver the stent. The stents are available in a variety of diameters and lengths.

**5. Intended Use:**

The proposed Ultraflex Esophageal Stent System is intended for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.

The proposed Ultraflex Diamond Biliary Stent System is indicated for palliative treatment of patients with malignant biliary strictures.

The proposed Ultraflex Tracheobronchial Stent System is intended for use in the treatment of tracheobronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted.

**6. Technological Characteristics:**

There are no differences in the technological characteristics between the proposed and predicate devices. The purpose of this Special 510(k) is to request a labeling claim that the Ultraflex stents are MRI safe and MRI compatible.

**7. Performance Data:**

Bench testing was conducted to support the MRI safety and compatibility claim.

**8. Conclusion:**

BSC has demonstrated that the proposed Esophageal, Biliary and Tracheobronchial Ultraflex stents are substantially equivalent to BSC's currently marketed Esophageal, Biliary and Tracheobronchial Ultraflex stents.



OCT 12 2001

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Kathleen Morahan  
Principal Regulatory Specialist  
Boston Scientific Corporation  
One Boston Scientific Place  
Natick, Massachusetts 01760-1537

Re: K012883

Trade/Device Name: Ultraflex™ Stent Systems (i.e., Ultraflex Esophageal Stent System, Ultraflex Diamond Biliary Stent System and Ultraflex Tracheobronchial Stent System)

Regulation Numbers: 21 CFR §878.3610, §876.5010 and §878.3720

Regulation Names: Esophageal prosthesis, Biliary catheter and accessories, Tracheal prosthesis

Regulatory Class: II

Product Codes: 79 ESW, 78 FGE and 79 JCT

Dated: October 1, 2001

Received: October 2, 2001

Dear Ms. Morahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that biliary stents will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the Ultraflex Diamond Biliary Stent System's labeling:

The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. *Please note:* This response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally §809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR §807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bernard E. Statland", with a stylized flourish at the end.

Bernard E. Statland, M.D., Ph.D.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): K012883

Device Name: Ultraflex Diamond Biliary Stent System

FDA's Statement of the Indications For Use for device:

The Ultraflex Diamond Biliary Stent System is indicated for palliative treatment of patients with malignant biliary strictures.

Prescription Use ✓ OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)

Nancy C. Brogdon  
(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K012883

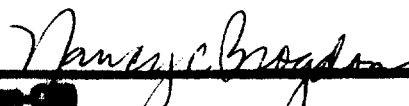
510(k) Number (if known): K012883

Device Name: Ultraflex™ Esophageal Stent System

Indication for Use:

The Ultraflex Esophageal Stent is indicated for use in esophageal strictures caused by intrinsic and/or extrinsic malignant tumors.

Prescription Use ☒ OR Over-The-Counter Use ☐  
(Per 21 CFR 801.109)

  
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(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices  
510(k) Number K012883

510(k) Number (if known): K012883

Device Name: Ultraflex™ Tracheobronchial Stent System

Indication for Use:

The Ultraflex Tracheobronchial Stent System is indicated for treatment of tracheobronchial strictures produced by malignant neoplasms or in benign strictures after all alternative therapies have been exhausted.

Prescription Use ☒ OR Over-The-Counter Use ☐  
(Per 21 CFR 801.109)

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